

REMARKS

After entry of the subject amendment, claims 1, 4-6, 8-12, 28-34, and 36-43 remain pending the subject application with claims 1 and 12 in independent form. More specifically, in the subject amendment, claims 1, 6, 9, 12, 29, 32, and 33 have been amended, claims 2 and 35 have been canceled, and claims 38-43 have been added. Notably, claims 3, 7, and 13-27 were already canceled in a previous amendment. There is full support in the specification as originally filed for the amendments to the claims and for the added claims. Accordingly, no new matter has been introduced.

Claims 1, 2, 4, 6, 8-12, and 28-37 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Wellisz et al. (United States Patent No. 6,511,482). Claim 5 stands rejected under § 103(a) as being unpatentable over the '482 patent to Wellisz et al. in view of Hair (United States Patent No. 6,197,037). Finally, claims 10 and 11 stand rejected under § 103(a) as being unpatentable over the '482 patent to Wellisz et al. in view of Pohndorf et al. (United States Patent No. 5,904,683). The Applicant respectfully submits that these rejections are obviated and that the pending claims are allowable in view of the amendments to claims 1 and 12.

Both independent claims, specifically claims 1 and 12, have been amended to clarify the invention in view of the prior art, either alone or in combination. As such, the independent claims both require a very specific physical structure for the extension and for the support element. More specifically, claim 1 has been amended to clarify and recite, among other components:

- (1) that the extension of the implant includes an end;
- (2) that the extension extends substantially at a right angle from the lower side of the support element; and
- (3) that the extension extends substantially straight between the support element and the end.

Claim 12 has also been amended to clarify and to recite, among other components:

- (1) that the extension of the implant includes an end; and
- (2) that the support element and the extension form a T-shaped structure in cross-section *between the support element and the end* (emphasis added).

As explained throughout the original specification and as disclosed throughout the Figures, the particular structural arrangement for the extension and the support element as outlined above, is pertinent to the ability of the self-retaining implant of the preferred embodiment to optimally and to adequately anchor the implant to the bone cover, which is ultimately attached to the skull via the implant. More specifically, as for the structure of the extension, referring to page 4, line 27 – page 5, line 3 of the original specification, the preferred extension “function[s] as an abutment” and “allows for precise driving-in of the spike.” Due to the preferred ‘straightness’ of the extension, the extension prevents unwanted excessive driving in of the spike once the extension comes to rest against lateral regions of the bone cover or bone fragment. Without the straightness of the extension, the spike may be driven into the bone cover or bone fragment too far which is obviously undesirable.

As for the structure of the support element, referring to page 5, lines 5 – 24, the design of the two support arms extending in opposite directions from the extension (claim 1) and the design of the T-shaped structure formed by the support element and the extension (claim 12) are advantageous because these designs, in combination with the spike (or spikes) that is driven laterally into the bone cover, “allows for particularly reliable securing of the implant to the bone cover” (*see, in particular, page 5, lines 16-22*). Without the two support arms and without the T-shaped structure working in conjunction with the at least one spike, the self-retaining implant may not be suitably secured to the bone cover.

In view of the amendments to independent claims 1 and 12, it is now even more evident that the '482 patent to Wellisz et al. (nor any of the other prior art of record) does not render obvious the invention as now claimed. The extension of the '482 patent, identified by the Examiner as element 223 in Figure 10, does not extend substantially straight between the support element and the end of the extension. Furthermore, the extension of the '482 patent does not, in combination with the support element, form a T-shaped structure between the support element and the end of the extension. Admittedly, Figure 10 of the '482 patent discloses what appears to be substantially right angles between the lower side of the support element and the extension. However, proceeding downward in the orientation of Figure 10, immediately after the substantially right angles, the structure of the extension deviates and is clearly extensively curved. As such, the extension of the '482 patent clearly does not extend *straight* between the support element and the end of the extension (relating to claim 1) and clearly does not establish a complete T-shaped structure between the support element and the end (relating to claim 12). As such, the extension of the '482 patent is entirely deficient in terms of providing an abutment that allows for precise driving-in of the spike into the bone cover or bone fragment.

Furthermore, in the context of newly added claims 38 and 42, it is worthy to note that the extension of the '482 patent, element 23 in Figure 5 and element 223 in Figure 10, is resilient and flexible such that it is capable of achieving a spring-like effect (*see, in particular, column 4, lines 58-59 and column 5, lines 50-51*). Thus, the extension 23, 223 of the '482 patent is not inelastic and does not extend rigidly from the lower side of the support element. Without the rigid extension, the extension of the '482 patent clearly cannot provide a sufficient abutment for controlling the extent of penetration of the spike.

Importantly, in view of the significant differences between the claimed invention and the implant of the '482 patent, the Applicant has thoroughly reviewed the '482 patent in its entirety and there is no disclosure, teaching, or suggestion in this document to modify the extension of the '482 patent to arrive at an implant having an extension as

now claimed in the present application. That is, the '482 patent does not provide any disclosure, teaching, or suggestion of an extension that (1) extends substantially at a right angle from the support element *and* straight between the support element and an end of the extension, or that (2) establishes a complete T-shaped structure between the support element and the end of the extension. Figure 5 of the '482 patent discloses an extension that does extend straight; however, this extension is not at a right angle relative to the support element and there is no such teaching for the extension to extend at a right angle. In fact, the '482 patent only teaches that the angle α in Figure 5 can vary from 50 to 60° and not anywhere near 90° (see Figure 5 and column 4, lines 51-53).

Finally, in an anticipatory fashion, the Applicant reemphasizes the impropriety of any potential combination with United States Patent No. 6,302,884. Due to reasoning already discussed at length in response to a previous Office Action, the '884 patent is irrelevant prior art. In other words, any combination of the '482 and '884 patents would be inappropriate because the '884 patent does not disclose or anywhere even teach a support element having two support arms extending in opposite direction from the extension forming a T-shape with the extension. As such, the '482 patent and the '884 patent teach structures for attaching a self-retaining implant to a bone cover or bone fragment or skull that are mutually exclusive from one another.

In view of the amendments to independent claims 1 and 12 and in view of the remarks set forth above, it is respectfully submitted that the § 103(a) rejections are obviated and that no prima facie case of obviousness can be established against independent claims 1 and 12, as now amended. Furthermore, the remaining claims depend, either directly or indirectly, from the non-obvious features of these independent claims such that these claims are also allowable.